

## § 725.36

## 40 CFR Ch. I (7–1–14 Edition)

(e)(1) EPA will consider the objections filed by the submitter. The Director, or a designee, will determine whether the submission was complete or incomplete, or whether to modify the requirements for completing the submission. EPA will notify the submitter in writing of EPA's response within 10 days of receiving the objections.

(2) If the Director, or a designee, determines, in response to the objection, that the submission was complete, the review period will be deemed suspended on the date EPA declared the submission incomplete, and will resume on the date that the submission is declared complete. The submitter need not correct the submission as EPA originally requested. If EPA can complete its review within the review period beginning on the date of the submission, the Director, or a designee, may inform the submitter that the running of the review period will resume on the date EPA originally declared it incomplete.

(3) If the Director, or a designee, modifies the requirements for completing the submission or concurs with EPA's original determination, the review period will begin when EPA receives a complete submission.

(f) If EPA discovers at any time that a person submitted materially false or misleading statements in information submitted under this part, EPA may find that the submission was incomplete from the date it was submitted, and take any other appropriate action.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 788, Jan. 6, 2010]

### § 725.36 New information.

(a) During the review period, if a submitter possesses, controls, or knows of new information that materially adds to, changes, or otherwise makes significantly more complete the information included in the MCAN or exemption request, the submitter must send that information within 10 days of receiving the new information, but no later than 5 days before the end of the review period. The new information must be sent in the same manner the original notice or exemption was sent, as described in § 725.25(c)(1), (c)(2), and (c)(3).

(b) The new submission must clearly identify the submitter, the MCAN or exemption request to which the new information is related, and the number assigned to that submission by EPA, if known to the submitter.

(c) If the new information becomes available during the last 5 days of the review period, the submitter must immediately inform the EPA contact for that submission by telephone of the new information.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010]

### § 725.40 Notice in the Federal Register.

(a) *Filing of FEDERAL REGISTER notice.* After EPA receives a MCAN or an exemption request under this part, EPA will issue a notice in the FEDERAL REGISTER including the information specified in paragraph (b) of this section.

(b) *Contents of notice.* (1) In the public interest, the specific microorganism identity listed in the submission will be published in the FEDERAL REGISTER unless the submitter has claimed the microorganism identity confidential. If the submitter claims confidentiality, a generic name will be published in accordance with § 725.85.

(2) The categories of use of the microorganism will be published as reported in the submission unless this information is claimed confidential. If confidentiality is claimed, the generic information which is submitted under § 725.88 will be published.

(3) A list of information submitted in accordance with § 725.160(a), § 725.255, § 725.260, § 725.355, or § 725.455, as appropriate, will be published.

(4) The submitter's identity will be published, unless the submitter has claimed it confidential.

(c) *Publication of exemption decisions.* Following the expiration of the appropriate review period for the exemption request, EPA will issue a notice in the FEDERAL REGISTER indicating whether the request has been approved or denied and the reasons for the decision.

### § 725.50 EPA review.

(a) *MCANs.* The review period specified in section 5(a) of the Act for MCANs runs for 90 days from the date the Document Control Officer receives

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a complete submission, or the date EPA determines the submission is complete under § 725.33, unless the Agency extends the review period under section 5(c) of the Act and § 725.56.

(b) *Exemption requests.* The review period starts on the date the Document Control Officer receives a complete exemption request, or the date EPA determines the request is complete under § 725.33, unless the Agency extends the review period under § 725.56. The review periods for exemption requests run as follows:

(1) *TERAs.* The review period for TERAs is 60 days.

(2) *TMEs.* The review period for TMEs is 45 days.

(3) *Tier II exemption requests.* The review period for Tier II exemption requests is 45 days.

### § 725.54 Suspension of the review period.

(a) A submitter may voluntarily suspend the running of the review period if the Director, or a designee, agrees. If the Director does not agree, the review period will continue to run, and EPA will notify the submitter. A submitter may request a suspension at any time during the review period. The suspension must be for a specified period of time.

(b)(1) *Request for suspension.* A request for suspension may only be submitted in a manner set forth in this paragraph. The request for suspension also may be made orally, including by telephone, to the submitter's EPA contact for that notice, subject to paragraph (c) of this section.

(2) *Submission of suspension notices.* EPA will accept requests for suspension only if submitted in accordance with this paragraph. Requests for suspension, must be generated, completed, and submitted to EPA (via CDX) using e-PMN software. See 40 CFR 720.40(a)(2)(ii) for information on how to obtain e-PMN software.

(c) An oral request for suspension may be granted by EPA for a maximum of 15 days only. Requests for longer suspension must only be submitted in the manner set forth in this paragraph.

(d) If the submitter has not made a previous oral request, the running of the notice review period is suspended

as of the date of receipt of the CDX submission by EPA.

[62 FR 17932, Apr. 11, 1997, as amended at 75 FR 789, Jan. 6, 2010; 78 FR 72828, Dec. 4, 2013]

### § 725.56 Extension of the review period.

(a) At any time during the review period, EPA may unilaterally determine that good cause exists to extend the review period specified for MCANs, or the exemption requests.

(b) If EPA makes such a determination, EPA:

(1) Will notify the submitter that EPA is extending the review period for a specified length of time and state the reasons for the extension.

(2) For MCANs, EPA may issue a notice for publication in the FEDERAL REGISTER which states that EPA is extending the review period and gives the reasons for the extension.

(c) The total period of the extension may be for a period of up to the same length of time as specified for each type of submission in § 725.50. If the initial extension is for less than the total time allowed, EPA may make additional extensions. However, the sum of the extensions may not exceed the total allowed.

(d) The following are examples of situations in which EPA may find that good cause exists for extending the review period:

(1) EPA has reviewed the submission and is seeking additional information.

(2) EPA has received significant additional information during the review period.

(3) The submitter has failed to correct a submission after receiving EPA's request under § 725.32.

(4) EPA has reviewed the submission and determined that there is a significant possibility that the microorganism will be regulated under section 5(e) or section 5(f) of the Act, but EPA is unable to initiate regulatory action within the initial review period.

### § 725.60 Withdrawal of submission by the submitter.

(a)(1) *Withdrawal of notice by the submitter.* A submitter may withdraw a notice during the notice review period by submitting a statement of withdrawal